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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,358	07/25/2003	Peter Migaly	290194-00001	2456

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EXAMINER	
OLSON, ERIC	
ART UNIT	PAPER NUMBER
1623	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/01/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/627,358	MIGALY, PETER	
	Examiner	Art Unit	
	Eric S. Olson	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38,41-43 and 48-105* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-38, 41-43, and 48-105* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

This office action is a response to applicant's amendment submitted January 22, 2007 wherein claims 1-3, 6, 14, 15, 41-43, 48, 49, and 51-54 are amended, claims 39, 40, and 44-47 are cancelled, and new claims 55-105 are introduced. This application claims priority to provisional application 60/319436, filed July 30, 2002.

Claims 1-38, 41-43, and 48-105 are pending in this application.

Claims 1-38, 41-43, and 48-105 as amended are examined on the merits herein.

Applicant's amendment, submitted January 22, 2007, with respect to the rejection of instant claim 6 under 35 USC 112, second paragraph, for being indefinite for reciting the names, ORG 5222 and SM-9018, has been fully considered and found to be persuasive to remove the rejection as the claims as amended no longer recite said limitations. Therefore the rejection is withdrawn.

Applicant's amendment, submitted January 22, 2007, with respect to the rejection of instant claims 42, 48, 53, and 54 under 35 USC 112, first paragraph, for reciting the term, "preventing," has been fully considered and found to be persuasive to remove the rejection as the claims as amended no longer recite this term. Therefore the rejection is withdrawn.

Applicant's amendment, submitted January 22, 2007, with respect to the rejection of instant claims 1-2, 4-6, 9, 11, 13, 14, 16, 18, 20-22, 24-26, 28-30, 32-35, 37-

38, 42, 48, 49, 51, 53, and 54 under 35 USC 102(b), for being anticipated by Tollefson has been fully considered and found to be persuasive to remove the rejection as the claims as amended recite the further limitation, "at a time selected from the group consisting of, as an initial treatment, as soon as possible, and upon presentation of said patient to a physician or other health care provider." These limitations are not spelled out explicitly by Tollefson. Therefore the rejection is withdrawn.

Applicant's amendment, submitted January 22, 2007, with respect to the rejection of instant claims 1-2, 4-6, 9-11, 13, 14, 37-38, 42, 48, 51, 53, and 54 under 35 USC 102(e), for being anticipated by Faour has been fully considered and found to be persuasive to remove the rejection as the claims as amended recite the further limitation, "at a time selected from the group consisting of, as an initial treatment, as soon as possible, and upon presentation of said patient to a physician or other health care provider." These limitations are not spelled out explicitly by Faour et al. Therefore the rejection is withdrawn.

Applicant's amendment, submitted January 22, 2007, with respect to the rejection of instant claims 3-6, 9, 49, 50, and 51 under 35 USC 102(b), for being anticipated by George et al. has been fully considered and found to be persuasive to remove the rejection as the claims as amended require that the patient be non-psychotic. Therefore the rejection is withdrawn.

Applicant's amendment, submitted January 22, 2007, with respect to the rejection of instant claims 1-2, 4, 7, 9, 11-15, 37, 38, 42, 48, and 51-54 under 35 USC 102(e), for being anticipated by Chappell et al. has been fully considered and found to be persuasive to remove the rejection as the claims as amended recite the further limitation, "at a time selected from the group consisting of, as an initial treatment, as soon as possible, and upon presentation of said patient to a physician or other health care provider." These limitations are not spelled out explicitly by Chappell et al. Therefore the rejection is withdrawn.

An examination of this application reveals that applicant is unfamiliar with patent prosecution procedure. While an inventor may prosecute the application, lack of skill in this field usually acts as a liability in affording the maximum protection for the invention disclosed. Applicant is advised to secure the services of a registered patent attorney or agent to prosecute the application, since the value of a patent is largely dependent upon skilled preparation and prosecution. The Office cannot aid in selecting an attorney or agent.

A listing of registered patent attorneys and agents is available on the USPTO Internet web site http://www.uspto.gov in the Site Index under "Attorney and Agent Roster." Applicants may also obtain a list of registered patent attorneys and agents located in their area by writing to the Mail Stop OED, Director of the U. S. Patent and Trademark Office, PO Box 1450, Alexandria, VA 22313-1450

Claim Objections

Applicant is advised that should claim 1 or 2 be found allowable, claims 59, 60-62, 98-103, and 109-118 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Said claims introduce no new limitations to claims 1 and 2 besides stating various motivations for the treatment such as, "for resisting suicide," or, "for the benefit of the group of patients." These so-called limitations do not introduce any new steps into the method of the original claims, alter any existing steps, or materially alter the patient population. Therefore they are seen to be identical to claims 1 and 2, and thus to be substantial duplicates thereof.

The following rejection, of record in the previous office action, is maintained:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-15, 36-38, 41-43, 48-74, 95-106, and 109-118 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating depression, cognitive distortions, smoking cessation, or nicotine withdrawal comprising administering certain antidepressants defined in the specification

and prior art in combination with certain specific atypical antipsychotic drugs known to be useful for improving therapeutic outcomes in depression, does not reasonably provide enablement for such a method involving any antidepressant and any antipsychotic. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The Applicant's attention is drawn to *In re Wands*, 8 USPQ2d 1400 (CAFC1988) at 1404 where the court set forth eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) The nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention: The claimed invention is a method of treating depression and other disorders by administering a combination of two drugs. It is claimed that the antipsychotic drug improves the therapeutic outcome even in patients not suffering from psychotic symptoms.

The state of the prior art: Combination therapy with antidepressants and atypical antipsychotic drugs has been taught in the prior art. The antipsychotic drugs known to be useful in this method are of the newer, atypical variety. No general theory has been provided which would explain the usefulness of atypical antipsychotic drugs for treating

depression, or determining which specific drugs are the most likely to be useful. Although a number of drug combinations have been tested and found to be useful, particularly combinations of a serotonin reuptake inhibitor with an atypical antipsychotic, many drugs of both types have not been tested. In particular, typical antipsychotics and dopamine system stabilizers such as aripiprazole have not been tested in the claimed methods.

The relative skill of those in the art: The relative skill of those in the art is high.

The predictability or unpredictability of the art: In the absence of any general theory explaining the action of atypical antipsychotic drugs to enhance therapeutic outcomes with antidepressants, it is not possible to predict the efficacy of any particular antipsychotic for this purpose absent experimental data. Because the terms antidepressant and antipsychotic both encompass a large number of drugs of varying structures and methods of action, and because antipsychotic drugs differ significantly from each other as disclosed in Applicant's specification, (p. 13, lines 11-15) no one example of group of related examples can be predictive for demonstrating the effectiveness of antidepressants combined with antipsychotics generally. Thus the effectiveness of a particular combination therapy of an antidepressant and an antipsychotic for the treatment of depression, cognitive distortions, smoking cessation, or nicotine withdrawal is unpredictable.

The Breadth of the claims: The claimed invention encompasses combination therapies of any antidepressant with any antipsychotic. In particular, it encompasses combinations in which the antipsychotic is a typical or an atypical antipsychotic, or a

dopamine system stabilizer. While some of the aforementioned claims recite specific antidepressants or specific antipsychotic agents, they are all generic to at least one component of the combination.

The amount of direction or guidance presented: Two hypothetical cases are given in order to illustrate possible uses of the claimed therapeutic method. (p. 16-17)

The presence or absence of working examples: No working examples of the claimed therapeutic methods is provided by Applicant.

Note that lack of working examples is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art such as antidepressant/antipsychotic combination therapy. See MPEP 2164.

The quantity of experimentation necessary: In order to practice the claimed invention, one skilled in the art would be required to determine the extent of antidepressants and antipsychotics useful in said methods. Because Applicant has provided no working examples, and because the state of the art is unpredictable, many different combinations would need to be tested in order to provide a comprehensive understanding of which combinations are or are not useful in the claimed method. These experiments would be repeated for each combination in animal models of depression, cognitive distortions, and nicotine addiction, in order to establish their suitability as therapeutic methods. It should be noted that evaluating psychological disorders such as depression and cognitive distortions in animals is more difficult than evaluating a therapy for a nonpsychological condition such as cancer or arthritis. Animal experiments include, along with the actual administration of the potential

pharmaceutical compound and collection and analysis of data, additional burdens associated with compliance with animal welfare regulations, care, feeding, and other maintenance of the animals, dissection of dead animals to collect data, and disposal of dead animals after the protocol is finished. Because of the unpredictability of the art and the lack of any generalized method for predicting the pharmacological properties of any arbitrarily chosen molecule, these animal experiments would need to be repeated many times, and involve the maintenance, killing, and disposal of many experimental animals, to establish the suitability or lack thereof for each compound found to possess the desired activity in vitro.

The scale of animal testing described in the preceding paragraphs would present an undue amount of unpredictable experimentation to require of anyone wishing to practice the invention.

Genentech, 108 F.3d at 1366, sates that, "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion." And "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, in view of the Wands factors, as discussed above, particularly the unpredictability of the art and the lack of guidance or working examples, Applicants fail to provide information sufficient to practice the claimed invention with every possible antidepressant and antipsychotic.

Response to Argument: Applicant's argument, submitted January 22, 2007, with respect to the above rejection has been fully considered and not found to be persuasive

to remove the rejection. Applicant argues that the claimed invention falls within the common and routine practice of off-label administration of FDA-approved drugs to different patient populations from those for which they were originally approved, and which has already been practiced with the claimed drugs for different indications. This argument is persuasive only for those antidepressants and antipsychotics which are in fact in common use for other indications and can reasonably be prescribed off-label. The claims as written use functional language which is not limited only to drugs currently known, such as serotonin reuptake inhibitors, dopamine system stabilizers, and the like. Rather, the claims as written include methods of treatment using any compound whatsoever that happens to have any antidepressant or antipsychotic activity. In all likelihood, many such compounds are not yet known, much less prescribed and available for off-label use.

Applicant's statements with regard to the theory behind the claimed invention have been considered, but are not relevant to the issue of functional language raised above. The problem for a skilled practitioner in the art, as described in the previous paragraph, is that drug species have been claimed by the functional language of instant clams 1-3 that are not currently known to have any psychiatric utility. A skilled practitioner cannot reasonably be expected to prescribe off-label a compound which he does not know to have a therapeutic effect, and whose psychiatric effects and interactions with other drugs have never been observed in any human or animal subject for any indication.

Applicant's argument with respect to Einstein's theory of relativity is not relevant to the instant case because Einstein developed no practical application for the theory of relativity. Facts of nature (which are always unpatentable) are harder to clearly and definitively prove than inventions having a specific, practical utility. If Einstein had invented a process, machine, manufacture, or composition of matter based on the theory of relativity possessing a real-world utility, the enablement of said invention would likely have been proven well before the theory of relativity itself had been proven and would not have required atomic clocks to test. Therefore Applicant's invention cannot be compared to a scientific theory.

Applicant also notes that the cost of a study of the clinical efficacy of a drug is prohibitive and that such studies are not required for off-label use. As stated earlier, Applicant's functional language encompasses not only those drugs currently on the market and available for off-label use, but also those which have not yet been discovered. Even the simplest *in vitro* and *in vivo* experiments needed to discover new classes of antidepressants and antipsychotics (referring to high-throughput screens used in the earliest stages of drug discovery, and not to $40 million government-funded clinical studies) would, when repeated for every compound under the sun, involve a burden of experimentation, including synthesis and screening of millions of compounds at least and follow-up experiments on all promising leads, that would constitute undue and unpredictable experimentation. Applicant should note that none of this experimentation is necessary for the off-label use of currently known drugs (e.g.

fluoxetine or ziprasidone) but only for drugs not currently known in the art for any psychiatric use.

Applicant further argues that the relevant art is predictable, and in fact crowded, as evidenced by the many drugs on the market and their routine off-label use. While this statement is true as regards those classes of drugs already known to be psychiatric drugs, Applicant's open-ended claim language reaches far beyond the known and predictable art. Such open-ended language greatly reduces the predictability of an invention.

For these reasons, the rejection is upheld and made **FINAL**. With regards to new claims 55-118, the rejection of these claims was necessitated by Applicant's amendment and is thus properly made final.

Applicant's amendment, submitted January 22, 2007, necessitates the following new grounds of rejection:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-38, 49-52, 54, 56, 58, 61-94, and 97-107 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The base claims 3, 56, and 58 state that the antipsychotic drug is administered at a low dose. No

indication is given as to what a low dose is or what it is low relative to. No guidance is given in the claims or the specification to allow one skilled in the art to know, for example, how low the dose can be and still retain activity, or how high it can be and still be considered low. Therefore claim 3 and its dependant claims are indefinite.

Because Applicant's amendment necessitated the new ground of rejection above, the rejection is made **FINAL**.

Claims 55, 57, 60, and 63-108 recite the limitation "treating substantially all patients treated by said physician". There is insufficient antecedent basis for this limitation in the base claims 1 and 2. Said base claims include the negative limitation that the patient's depression not be psychotic or treatment-resistant. Therefore according to the base claims, the practitioner does not treat patients displaying psychosis or treatment resistance by this method. There is therefore insufficient antecedent basis in the parent claims for the new limitations introduced in claims 55 and 57.

Because Applicant's amendment necessitated the new ground of rejection above, the rejection is made **FINAL**.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 65 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's amendment submitted January 8, 2007 with respect to claim 65 has been fully considered and but is deemed to insert **new mater** into the claims since the specification as originally filed does not provide support for the active metabolite of risperidone. As the instant specification as filed contains no description of said metabolite or a method of using it as a therapeutic agent, the specification as originally filed does not provide support for the subject matter of instant claim 65. See *in re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972).

Because Applicant's amendment necessitated the new ground of rejection above, the rejection is made **FINAL**.

Claims 55, 57, 60, and 63-108 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's amendment submitted January 8, 2007 with respect to claims 55, 57, 60, and 63-108 has been fully considered and but is deemed to insert **new mater** into

the claims since the specification as originally filed does not provide support for a therapeutic method in which an antidepressant and an antipsychotic drug are administered to all patients treated by a physician or health care provider regardless of diagnosis or other considerations. The specification as filed (pp. 5-7, Summary of the Invention) only describes methods for treating patients having non-psychotic, non-treatment resistant depression, which is a specific clinical indication not shared by everyone who presents themselves to a health care provider, or other similarly specific conditions. See *in re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972).

Because Applicant's amendment necessitated the new ground of rejection above, the rejection is made **FINAL.**

Claims 55, 57, 60, and 63-108 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The Applicant's attention is drawn to *In re Wands*, 8 USPQ2d 1400 (CAFC1988) at 1404 where the court set forth eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:
(1) The nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims;

(6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention: The claimed method is a therapeutic method. Therapeutic methods, in order to meet the enablement requirement, must be disclosed in such a way that a skilled practitioner could reasonably be expected to practice said invention within the general guidelines of the art.

The state of the prior art: The medical art is a matter of life and death importance. In particular, it involves the administration of many drugs having severe and even potentially life-threatening side effects. As indicated by Applicant in his arguments submitted January 22, 2007, antipsychotic drugs possess such severe and potentially life-threatening side effects. Furthermore, antipsychotic drugs are only known to be of benefit from patients having a psychiatric disorder involving psychosis or psychotic-like symptoms. (such as disordered thinking, delusions, or hallucinations) Subjects not having these conditions will experience the side effects of the drugs without any benefit. Thus these drugs must not be prescribed without careful consideration of a patient's situation and whether the patient will benefit from them. A skilled practitioner would not, for example, sell antipsychotic drugs in a vending machine in the lobby of his office.

The usual practice in the art is to diagnose a patient with a particular disorder or symptom before deciding on a course of therapy, and to administer therapy only to patients reasonably believed to benefit from said therapy. The benefits of this approach include the avoidance of unnecessary side effects and the improved efficacy of therapy

resulting from administering to a patient a drug which is not suited to his condition. In addition to the issues mentioned above, automatic distribution of drugs to every patient carries a strong risk of enabling abuse of those drugs.

While it is a cliché that psychiatric disorders are merely extreme versions of common personality traits and that therefore, "everyone is a little bit crazy," it does not therefore follow that the average person would benefit from antipsychotic drugs. Even if this were the case, many patients would likely refuse therapy because they do not suffer appreciably as a result of their non-pathological personality quirks and do not particularly wish to take drugs, particularly drugs with serious side effects, in order to alter their personality.

The relative skill of those in the art: The relative skill of those in the art is high.

The predictability or unpredictability of the art: All sorts of people seek medical attention. A skilled practitioner cannot assume that every patient who walks into his office suffers from non-psychotic, non-treatment-resistant depression, or that all patients would benefit from antipsychotic drugs. Much of the job of a skilled practitioner involves diagnosis and determination of the best course of treatment for a patient. Once these steps have been removed form the decision of what therapy to pursue, the outcome of treatment is by definition highly unpredictable.

The Breadth of the claims: The instant claims are drawn to a method of administering a combination of an antidepressant and an antipsychotic drug to everyone who seeks treatment from the practitioner. This includes patients having a condition treatable by said drugs, patients having no condition treatable by said drugs, and

patients who are trying to obtain the drugs for purposes such as abuse or resale. Essentially, said claims involve treating antidepressants and antipsychotic drugs as unregulated, nonprescription drugs comparable to aspirin.

The amount of direction or guidance presented: Applicant's specification provides no evidence that antidepressants and antipsychotic drugs can be safely distributed to the general population without the carefully controlled regime of diagnosis and prescription that is currently in place for these drugs.

The presence or absence of working examples: Two hypothetical examples are provided. In both cases the patient is examined and diagnosed with non-psychotic depression. In neither case is medication administered in the absence of a diagnosis. In both cases medication is discontinued after a certain period of time, rather than being always administered for all patients.

Note that lack of working examples is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art such as the administration of drugs without diagnosis. See MPEP 2164.

The quantity of experimentation necessary: In order to practice the claimed invention, one skilled in the art would need to be in possession of antidepressants and antipsychotics lacking in side effects and suitable for administration to the general population of subjects presenting themselves to a physician, including patients not actually diagnosed with any psychiatric disorder. Up to now, the search for new psychiatric drugs has failed to uncover any which are safe to use outside of a careful diagnosis and prescription. As these drugs act on a very complex and central biological

system (i.e. the brain) there is no reasonable expectation that such drugs exist. If they do, discovering them would involve an intensive research program of screening millions of compounds against multiple targets involved in depression and psychosis and then testing the hits obtained from these screens fore side effects. The claimed invention therefore requires undue and unpredictable experimentation to practice.

Genentech, 108 F.3d at 1366, sates that, "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion." And "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, in view of the Wands factors, as discussed above, particularly the state of the prior art and the lack of guidance presented, Applicants fail to provide information sufficient to practice the claimed invention for the treatment of all patients.

Because Applicant's amendment necessitated the new ground of rejection above, the rejection is made **FINAL**.

Claims 43, 98, 109, 110 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating depression and associated conditions, and avoiding, protecting against, or remedying relapse or recurrence of depression, does not reasonably provide enablement for preventing depression or the progression or relapse thereof, or preventing suicide. The specification does not enable any person skilled in the art to which it pertains, or with

which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The Applicant's attention is drawn to *In re Wands*, 8 USPQ2d 1400 (CAFC1988) at 1404 where the court set forth eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) The nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention: The claimed invention is drawn to a method of preventing suicide, relapse of depression, or various complications thereof, by administering to a patient in need thereof a combination of an antidepressant and an antipsychotic.

The state of the prior art: Combination therapy with antidepressants and atypical antipsychotic drugs has been taught in the prior art for conditions such as psychotic depression or bipolar disorder. The antipsychotic drugs known to be useful in this method are of the newer, atypical variety. The prior art does not teach a method of preventing recurrence or relapse of depression through antidepressant/antipsychotic combination therapy, or of preventing suicide. As evidenced by the existence of treatment-resistant cases of depression, no therapy is 100% effective at preventing the progression, recurrence, or relapse of depression.

The relative skill of those in the art: The relative skill of those in the art is high.

The predictability or unpredictability of the art: Because the terms antidepressant and antipsychotic both encompass a large number of drugs of varying structures and methods of action, and because antipsychotic drugs differ significantly from each other as disclosed in Applicant's specification, (p. 13, lines 11-15) no one example of group of related examples can be predictive for demonstrating the effectiveness of antidepressants combined with antipsychotics generally.

Furthermore, depression denotes an observed symptom rather than an underlying condition. Different cases of depression differ from one another to the extent that a skilled practitioner must determine the best course of therapy empirically by administering one drug after another to a patient in order to find one which elicits a positive response. Thus it is highly unlikely that it is possible in all cases of depression to prevent progression, recurrence, or relapse with 100% certainty. Thus the prevention of progression, recurrence or relapse of depression is highly unpredictable.

In the case of cognitive distortions, smoking cessation, and nicotine addiction, the art is even more unpredictable. Both cognitive distortions and addictions have a strong psychological component, and the motivation of a patient to change is an essential factor in determining treatment outcome, and one which cannot be improved by any drug therapy. In particular, smoking cessation is rather difficult even with the aid of drug therapy, and most smokers who attempt to quit eventually suffer a relapse and start smoking again. Thus the treatment outcome in the treatment of cognitive distortions and nicotine addiction is highly unpredictable.

Suicide is an action rather than a pathological condition or symptom, and is the result of the interaction of various voluntary, involuntary, and semi-voluntary factors within a patient's condition. Any subject who displays a minimal level of functioning is physically capable of committing suicide, though motivation to do so is usually present only in extreme cases. Short of, for example, incapacitating doses of tranquilizers, no drug therapy can render a patient incapable of killing himself.

While certain drug therapies can affect the cognitive distortions that predispose a subject to suicide or to relapse in smoking cessation, these cannot be regarded as a 100% certain guarantee that the subject cannot, no matter what, smoke or commit suicide.

The Breadth of the claims: The claimed invention encompasses combination therapies of any antidepressant with any antipsychotic. In particular, it encompasses combinations in which the antipsychotic is a typical or an atypical antipsychotic, or a dopamine system stabilizer. **Prevention is interpreted to mean the complete, 100% effective elimination of any progression, recurrence, or relapse of the disease while the patient is maintained on the therapy**.

The amount of direction or guidance presented: Two hypothetical cases are given in order to illustrate possible uses of the claimed therapeutic method. (p. 16-17) No reason is given to suppose that he claimed methods are perfectly effective at preventing progression, recurrence, or relapse of any instance of major depressive disorder,

The presence or absence of working examples: No working examples of the claimed therapeutic methods is provided by Applicant.

Note that lack of working examples is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art such as the prevention of disease. See MPEP 2164.

The quantity of experimentation necessary: The short-term usefulness of a therapy for relief of symptoms is no guarantee of its long-term usefulness for prevention of disease. Because no guidance is given for the use of the claimed therapeutic method for the long-term prevention of disease, one skilled in the art wishing to practice the invention would be unable to do so without first gathering information as to the long-term effectiveness of the therapy. Furthermore, in order to prevent recurrence of depression, cognitive distortion, or nicotine addiction as described above, the claimed therapeutic method, which comprises nothing more than administering a drug, must be able to fully counteract the effects of genetics and psychology in order to prevent the subject from ever becoming depressed, having distorted cognition, or smoking again, regardless of the subject's motivation, or any environmental stresses which may encourage the re-emergence of the subject's condition. Such a method would represent a significant novel improvement beyond anything disclosed in the prior art or in Applicant's disclosure, particularly in light of the high relapse rate for smokers attempting to quit.

In order to develop such a method in the absence of any existing data, one skilled in the art, in order to practice the invention, would undertake long-term

human or animal tests in order to study the effectiveness of the claimed therapy for preventing recurrence or relapse after the initial recovery. Animal experiments include, along with induction of the disease state, administration of the potential pharmaceutical compound and collection and analysis of data, additional burdens associated with compliance with animal welfare regulations, care, feeding, and other maintenance of the animals, dissection of dead animals to collect data, and disposal of dead animals after the protocol is finished. Human tests impose additional ethical and regulatory burdens.

Performing these studies with no guidance from Applicant or from the prior art is an undue amount of experimentation needed in order to practice the full range of the claimed invention.

Genetech, 108 F.3d at 1366, sates that, "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion." And "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, in view of the Wands factors, as discussed above, particularly the lack of precedent in the art for prevention of relapse and the lack of guidance from Applicant's disclosure, Applicants fail to provide information sufficient to practice the claimed invention for the prevention of regression, recurrence, or relapse of disease.

Response to Argument: Applicant's argument, submitted January 22, 2007, as applied to the above rejection has been fully considered and not found to be persuasive to remove the rejection. Applicant's arguments are all based on the interpretation that the term, "prevention" denotes a treatment that is not necessarily one hundred percent

successful and need not be permanent in its effects. Applicant cites certain examples, such as the approval of prenatal vitamins for the "prevention" of cleft palate and aspirin for the "prevention" of heart attack. This line of argument is not persuasive because the term "prevention" has various meanings in the medical and legal art as well as various meanings to laypeople. For the purposes of patent prosecution, the term "prevention" is used as a legal term specifically referring to the perfect and absolute blocking of any possibility of a disorder in the future. For these purposes, prenatal vitamins do not prevent cleft palate, aspirin does not prevent heart attack, and vaccines do not prevent influenza.

Therefore the rejection is deemed proper and maintained. Because Applicant's amendment necessitated this rejection, the rejection is made **FINAL**.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6, 9, 11, 13, 14, 16-18, 20-22, 24-26, 28-30, 32-37, 41-43, 48, 49, 51, 53, 54-68, 70, 72, 73, 75-77, 79-81, 83-85, 87-89, 91-104, and 109-118 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tollefson. (PCT international publication WO99/61027, included by applicant with PTO-1449) Tollefson discloses a method of treating depression by administering both a serotonin reuptake inhibitor and

an atypical antipsychotic. While one embodiment of this invention is a method of treating treatment-resistant depression, another embodiment is a method of providing rapid onset treatment of depression to a patient, (p. 2, lines 10-13) which is drawn to cases which have not demonstrated treatment resistance. Specific atypical antipsychotic drugs which may be administered in this method are olanzapine, clozapine, risperidone, sertindole, quetiapine, and ziprasidone. (p. 3) Specific serotonin reuptake inhibitors which may be used are fluoxitene, duloxetine, venlafaxine, milnacipran, citalopram, fluvoxamine, paroxetine, and sertaline, (p. 4, line 5 – p. 5, line 14) Recommended dosages are given on p. 13. Tollefson does not disclose a method in which the antipsychotic is administered according to the dosage levels disclosed in instant claims 36 and 95. Tollefson does not explicitly disclose a method of administering the claimed treatments as an initial treatment, as soon as possible, or upon presentation to a physician or other health care provider, or a method wherein treatment is given for preventing suicide. Tollefson also does not explicitly disclose a method of treating cognitive distortions as defined by Applicant's specification on p. 15, lines 9-14.

It would have been obvious to one of ordinary skill in the art to administer the drugs in the methods of Tollefson et al. at the dosages describes in instant claims 36 and 95. It would have been obvious to one of ordinary skill in the art at the time of the invention to administer the therapeutic method of Tollefson to a patient as initial treatment as soon as possible, and to provide treatment in order to prevent suicide, as described in instant claims 39, 41, and 43, and to treat cognitive distortions according to

instant claims 3 and 49. One of ordinary skill in the art would have been motivated to practice the therapeutic method in this way because Tollefson discloses that his method is useful for providing rapid onset treatment, and thus for providing immediate treatment for emergency cases where time is of the essence, such as those in which the subject is at serious risk of suicide. One of ordinary skill in the art would have been motivated to use the doses described in instant claims 36 and 95 because the ranges disclosed in this claim overlap with those disclosed on p. 13 of Tollefson et al. One of ordinary skill in the art would have been motivated to use the method for treating cognitive distortions because cognitive distortions as defined by Applicant are often associated with depression. One of ordinary skill in the art would reasonably have expected success in using the dosages of instant claim 36 because these dosages overlap with those taught by Tollefson et al. and because adjusting dosages within the general range known in the prior art is well within the level of ordinary skill in the art. One of ordinary skill in the art would reasonably have expected success in administering treatment as soon as possible to prevent suicide because suicide is known to correlate strongly with depression, and because treating a subject for a serious condition as son as possible is a generally recognized practice in the art. One of ordinary skill in the art would reasonably have expected success in treating cognitive distortions because treating the associated depression would lead to improvement in the associated cognitive distortions.

With respect to the various motivations included in the claim limitations, for example, claims 109-118, these limitations describe various motivations for

administering the claimed therapeutic agents to a patient suffering from depression or cognitive distortions, they do not materially alter the actual scope of the claims. Therefore they do not render the claims non-obvious over the prior art.

Thus the invention taken as a whole is *prima facie* obvious.

Response to Argument: Applicant's argument, filed September 22, 2007, as applied to the above rejection, has been fully considered and not found to be persuasive to remove the rejection. Applicant argues that Tollefson's disclosure is non-enabling because Tollefson's method is inferior to other prior art methods for treating rapid-onset depression known at the time. In particular, Applicant claims that, "while an inferior product can be patented, a drug that is harmful cannot be patented, and Tollefson failed to show that analysis." However, Applicant does not demonstrate that the method of Tollefson (and thus Applicant's own method) is in fact harmful, as opposed to merely being inferior to other treatment approaches. In order to be genuinely harmful, Applicant would need to show that there exists no case in which Tollefson's therapeutic method would be preferable to no treatment at all. While the drugs used have side effects, they are not so dangerous as to preclude any utility whatsoever, as evidenced by their use for other clinical indications. Therefore Tollefson's therapeutic method is considered to be enabled and legitimately cited as prior art.

Applicant further argues that depression is not included within the scope of cognitive distortion and cannot be equated with cognitive distortion, and that either one can exist without he other. However, the fact that these two terms are not identical does not preclude a method of treating cognitive distortion by treating depression. For

example, Applicant states that, "cognitive distortions may contribute to or worsen a number of illnesses like addictions, smoking, pathological gambling, impulse control disorders, anger, with consequent relationship conflicts, **major depression**, anxiety disorders, ..." Therefore a method of treating major depression can reasonably be considered a method of treating the symptoms of cognitive distortions. Furthermore, two disorders need not be exactly equivalent for the relief of one to relieve the other. While cognitive distortions and the risk of suicide may still linger and require further treatment, their magnitude and impact can be lessened by treating the associated depression, and this procedure would reasonably be considered a method of treating the cognitive distortions.

Applicant also argues that Tollefson does not disclose a low dose for any of the disclosed antipsychotics. In the absence of an actual dosage range, the term, "low dose" as recited in the instant claims is so broad and indefinite as to provide no meaningful limitation to the scope of the claims. As regards the specific doses recited in instant claims 36 and 95, Applicant argues that the dosage levels of the claimed invention are not obvious in view of Tollefson because the claimed invention functions by a different method from the prior art and one of ordinary skill in the art would not know that the low doses of the claimed invention are useful for this method. However, it is noted that the claimed dose ranges for olanzapine and risperidone overlap with the **preferred** dosage ranges disclosed by Tollefson. For these active agents at least, Tollefson clearly suggests using an especially preferred dosage of antipsychotic falling within Applicant's claimed range. Therefore, the claimed dosage levels for these two

agents are not considered to be so much lower than the prior art as to render the invention non-obvious.

For these reasons, the rejection is deemed proper. Because Applicant's amendment necessitated this rejection, the rejection is made **FINAL**.

Claims 8, 19, 23, 27, 31, 78, 82, 86, and 90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tollefson (PCT international publication WO99/61027) in view of Kelleher et al. (Reference included with PTO-892) The disclosure of Tollefson is discussed above. Tollefson does not disclose a method in which the atypical antipsychotic agent is aripiprazole.

Kelleher et al. discloses a number of atypical antipsychotics. One of these drugs is aripiprazole, described as an experimental atypical antipsychotic which is a partial agonist against D_2 receptors. (p. 257, right column, third paragraph) It should be noted that Kelleher appears in volume 16, no. 4 of the publication CNS Drugs, which is the April 2002 issue, and thus prior art against the instant application.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use aripiprazole as the atypical antipsychotic in the method of Tollefson et al. One of ordinary skill in the art would have been motivated to practice the invention in this manner because Kelleher et al. reveals that aripiprazole is useful for the same purposes as other atypical antipsychotics but with a reduced side effect profile. One of ordinary skill in the art would reasonably have expected success because Tollefson already discloses a method using any atypical antipsychotic agent generally.

Thus the invention taken as a whole is *prima facie* obvious. Because Applicant's amendment necessitated this rejection, the rejection is made **FINAL**.

Claims 1-2, 4-6, 9-11, 13-14, 37-38, 42, 48, 51, 53-64, 66, 69, 70, 73, 96-104, and 109-118 are rejected under 35 U.S.C. 103(a) as being obvious over Faour et al. (US patent application, 09/728276, Pub. No. 2001/0048943 A1, patented as US patent 6572890, cited in PTO-1449) Faour et al. discloses, "a method of treating **depression, anxiety**, and/or psychosis in a mammal, the method comprising administering an osmotic device which provides a controlled release of VFX [Venlafaxine, a selective serotonin and norepinephrine reuptake inhibitor] from its core and a rapid release of an anti-psychotic agent from an external coat," (p. 2, left column, paragraph 0020) anticipating instant claims 1-3, 9, 11, 13, 14, 37, 42, 48, 49, 51, 53, and 54. This osmotic device is meant for oral administration, anticipating instant claim 38. Various embodiments of the invention of Faour et al. include a number of atypical antipsychotic drugs, (p. 2, left column, paragraph 0022-0023) including those recited in instant claims 5, 6, and 10, for example. Faour et al. does not explicitly disclose a method of administering the claimed treatments as an initial treatment, as soon as possible, or upon presentation to a physician or other health care provider.

It would have been obvious to one of ordinary skill in the art at the time of the invention to administer the therapy disclosed by Faour et al. as an initial therapy and/or to administer it as soon as possible. One of ordinary skill in the art would have been motivated to practice the invention in this manner because Faour et al. already

discloses the treatment to be useful as a treatment for depression generally, and because it is standard practice in the art to administer a therapy promptly once it is indicated. One of ordinary skill in the art would reasonably have expected success because choosing a particular therapeutic regimen from among the various options available in the prior art is within the routine and ordinary level of skill in the art.

Thus the invention taken as a whole is *prima facie* obvious.

Response to Argument: Applicant's argument, filed September 22, 2007, as applied to the above rejection, has been fully considered and not found to be persuasive to remove the rejection. Applicant argues that one of ordinary skill in the art could not have used the method of Faour et al. to treat non-psychotic depression because use for this indication was not adequately disclosed or enabled by Faour et al. However, Faour et al. does disclose how to make the disclosed dosage form and which patient population (those suffering from depression) to administer it to. Therefore it is considered to disclose how to make and use the claimed invention. One of ordinary skill in the art would face no difficulties in practicing this method based on the disclosure of Faour et al. Applicant has provided no evidence which would demonstrate that the disclosure of Faour et al. is not enabling or that the invention described therein is not operable. Therefore the disclosure is judged to be enabled and the invention operable.

Furthermore, the fact that Faour et al. discloses embodiments directed to the treatment of depression or anxiety comorbid with psychosis does not prevent it from rendering obvious a method of treating non-psychotic depression. An embodiment of the prior art need not be a preferred embodiment in order to anticipate or render

obvious the claimed invention. Although no risk-benefit analysis or other specific guidance is given for the treatment of non-psychotic depression, the art is sufficiently predictable as regards known antidepressants and antipsychotic agents, as discussed at length by Applicant in his arguments with respect to the enablement of the claimed invention, that one of ordinary skill in the art would have been able to reliably use a known agent for these indication even without a detailed study providing exhaustive detail as to the effects in each and every possible indication.

Applicant also argues that Faour et al. does not disclose a low dose for any of the disclosed antipsychotics. In the absence of an actual dosage range, the term, "low dose" as recited in the instant claims is so broad and indefinite as to provide no meaningful limitation to the scope of the claims.

For these reasons, the rejection is deemed proper. Because Applicant's amendment necessitated this rejection, the rejection is made **FINAL**.

Claims 1-2, 4, 7, 9, 11-15, 37, 38, 42, 48, 51-62, 70-74, 96-105, and 109-118 are rejected under 35 U.S.C. 103(a) as being obvious over Chappell et al. (US patent application 10/001827, Pub. Number 2002/0094986 A1, of record in previous office action) Chappell et al. discloses a method of treating depression, anxiety, or psychosis in a mammal by administering a combination of an antidepressant, a D4 receptor antagonist, (an antipsychotic) and a pharmaceutically acceptable carrier. (p. 1, left column, paragraph 0002) General types of antidepressants which can be used are listed in paragraph 0021 and include norepinephrine reuptake inhibitors, serotonin

reuptake inhibitors, and monoamine oxidase inhibitors, among others, as described in instant claims 11-13. Norepinephrine reuptake inhibitors which may be used are listed in paragraph 0023 and include clomipramine among others, as in instant claims 14 and 15. The compounds used in this invention may all be administered orally, as described by instant claim 38. (p. 22, paragraphs 0460-0462) Chappell et al. does not explicitly disclose a method of administering the claimed treatments as an initial treatment, as soon as possible, or upon presentation to a physician or other health care provider.

It would have been obvious to one of ordinary skill in the art at the time of the invention to administer the therapy disclosed by Chappell et al. as an initial therapy and/or to administer it as soon as possible. One of ordinary skill in the art would have been motivated to practice the invention in this manner because Chappell et al. already discloses the treatment to be useful as a treatment for depression generally, and because it is standard practice in the art to administer a therapy promptly once it is indicated. One of ordinary skill in the art would reasonably have expected success because choosing a particular therapeutic regimen from among the various options available in the prior art is within the routine and ordinary level of skill in the art.

Thus the invention taken as a whole is *prima facie* obvious.

Response to Argument: Applicant's argument, filed September 22, 2007, as applied to the above rejection, has been fully considered and not found to be persuasive to remove the rejection. Applicant argues that Chappell et al. does not provide sufficient guidance or enablement to allow one of ordinary skill in the art to practice a method for treating non-treatment-resistant, non-psychotic depression. However, the art is

sufficiently predictable as regards known antidepressants and antipsychotic agents, as discussed at length by Applicant in his arguments with respect to the enablement of the claimed invention and the ability of one of ordinary skill in the art to practice off-label administration of known antipsychotic agents, that one of ordinary skill in the art would have been able to reliably use a known agent for these indication even without a detailed study providing exhaustive detail as to the effects in each and every possible indication. One of ordinary skill in the art would have recognized how to practice the claimed invention given the disclosure by Chappell et al. that these pharmaceutical combinations are suitable for the treatment of depression, including those cases of depression demonstrating neither psychosis nor treatment resistance.

Applicant also argues that Chappell et al. does not disclose a low dose for any of the disclosed antipsychotics. In the absence of an actual dosage range, the term, "low dose" as recited in the instant claims is so broad and indefinite as to provide no meaningful limitation to the scope of the claims.

Claims 106-108 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chappell et al. (US patent application 10/001827, Pub. Number 2002/0094986 A1, of record in previous office action) The disclosure of Chappell et al. is discussed above. Chappell et al. does not disclose a method in which the antidepressant is ketamine.

Berman et al. discloses that ketamine exerts antidepressant effects in human patients. (p. 351, second paragraph, right column, p. 352, left column, last paragraph, p. 353, right column, first paragraph)

It would have been obvious to one of ordinary skill in the art at the time of the invention to use ketamine as the antidepressant in the method of Chappell et al. One of ordinary skill in the art would have been motivated to practice the invention in this manner because Berman et al. reveals that ketamine is useful for the same purposes as the antidepressants recited by Chappell et al. One of ordinary skill in the art would reasonably have expected success because Ketmaine is already known to be useful as an antidepressant.

Thus the invention taken as a whole is *prima facie* obvious. Because Applicant's amendment necessitated this rejection, the rejection is made **FINAL**.

Conclusion

No claims are allowed in this application. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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